DETAILED ACTION

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed November 17, 2009 has been received and entered into the present application.

The amendment filed on October 19, 2009 is acknowledged. Claims 1-20 are under examination in the instant office action.

Applicants' arguments, filed on October 19, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All the dependent claims are included.

Claim 1 recites the limitation, "administering a haloarylpyrazole to the animal prior to exposure of the animal to ticks". It is unclear what is meant by "prior to exposure of the animal to ticks" because one cannot determine when is "prior to exposure to ticks". As soon as an animal is born, it will be exposed to ticks, thus the only way to practice the instant method is to administer the haloarylpyrazole right after birth or before birth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 11-12, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,189,053 (Issue Date: 2/23/1993).

US Patent 5,189,053 teaches the compounds of formula (I) as recited in the instant claim 1 (column 1, line 5-column 2, line 68 and claim 1) and the elected species, 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1H-pyrazole composition (column 21, lines 41-43, compound 22c), and a method of using the compounds for combating insects, acarids or animal endoparasites including ticks (claims 14-17 and column 3, lines 4-19). It further teaches the compounds are active systemically, especially against animal ecto- and endoparasites (column 3, lines 31-33) and compositions containing the compounds can be in the form of a preparation for oral (systemically applied), parenteral or dermal application, e.g. in the form of powders, solutions, suspensions, tablets, capsules, drenches, boluses, dips,

sprays, injectables or as food additives (column 4, lines lines 27-41). In addition, the reference further discloses that 100 mg/kg of compound 22c (elected species) is orally administered (considered as "systemically administered") to mice for parasitic infection *in vivo* test (column 29, lines 59-column 30-line 2). Furthermore, it teaches that the invention provides a method of combating pests such as insects and acarids at a locus or host for the pest, infested or liable to be infested therewith (column 3, lines 34-39), wherein a host liable to be infested is an uninfested animal. Thus, the reference encompasses the instant claim 22 as amended.

When the compound is administered to a animal for combating ticks as taught by the reference, the compound is administered prior to exposure of the animal to additional ticks and will necessarily deter additional ticks from infesting the animal. Thus, the teachings of the reference encompass the instant method.

As such, the instant claims are anticipated by US Patent 5,189,053.

Response to Applicant's arguments

In response to the argument that the specification clearly define "deterring" by the example, the example is not considered as a definition of the word "deterring", but a preferred embodiment, thus the broadest reasonable interpretation of "deterring" , which means preventing or inhibiting according to the definition of Merriam-Webster online dictionary, is still applied. Therefore, combating or killing ticks as taught by Willis reads on "deterring".

Even if "deterring were to be construed as "repelling", the reference teaches the use of the same compound for combating ticks in the animal infested or liable to be infested therewith (animal not yet infested by ticks), thus the deterring effect as Applicants argued necessarily occurs when an animal liable to be infested with ticks is treated with the compound for

combating ticks as taught by Willis. Even in the animal already infested with ticks, the treatment as taught by Willis necessarily deters attachment and feeding of additional ticks and the compound has been administered prior to exposure of the animal to additional ticks . Furthermore, the instant claims are drawn to method for deterring ticks from infesting an animal", not deterring (repelling) or preventing the attachment of ticks from the animal. The compound of the reference necessarily deters ticks from infesting the animal by killing ticks. Thus, the teachings of the reference encompass the instant method.

In the alternative, the following rejection under 35 U.S.C. 103(a) is made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent 5,189,053 in view of US patent 6,599,941 and US 2004/0067247.

US Patent 5,189,053 teaches the compounds of formula (I) as recited in the instant claim 1 (column 1, line 5-column 2, line 68 and claim 1) and the elected species, 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1H-pyrazole composition (column 21, lines 41-43, compound 22c), and a method of using the compounds for combating insects, acarids or animal endoparasites including ticks (claims 14-17 and column 3, lines 4-19). It further teaches the compounds are active systemically, especially against animal ecto- and endoparasites (column 3, lines 31-33) and compositions containing the compounds can be in the form of a preparation for oral (systemically applied), parenteral or dermal application, e.g. in the form of powders, solutions, suspensions, tablets, capsules, drenches, boluses, dips, sprays, injectables or as food additives (column 4, lines 27-41). In addition, the reference further discloses that 100mg/kg of compound 22c (elected species) is orally administered (considered as "systemically administered") to mice for parasitic infection *in vivo* test (column 29, lines 59-column 30-line 2). Furthermore, it teaches that the invention provides a method of combating pests such as insects and acarids at a locus or host for the pest, infested or liable to be infested therewith (column 3, lines 34-39), wherein a host liable to be infested is an uninfested animal.

The reference differs from the instant claims insofar as it does not specifically teaches deterring (i.e., repelling) tick from infestation to the animal and administration of the compound prior to exposure of the animal to ticks.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the haloarylpyrazole compound of US Patent 5,189,053 for deterring ticks from infestation to the animal since it was known to use an insecticide for both killing (combating) and repelling (deterring) insects such as ticks as evidenced by US 2004/0067247 (abstract) and US patent 6,599,941 (column 4, lines 28-43 and column 8, lines 8-20), which teach the use of an insecticide composition for killing and repelling insects. One of ordinary skill in the art would have be motivated to do so on the expectation that a compound effective for killing insects would also be useful for repelling the insects in view of the prior art. With regard to "administration of the compound prior to exposure of the animal to ticks", the skilled artisan would have reasoned to apply the compound prior to exposure to ticks for deterring ticks from infestation to the animal since this is what a person of ordinary skill in the corresponding art does.

With regard to claims 6-10 and 13-19, US Patent 5,189,053 does not specifically teaches that the animal is a dog or a cat and that the compound is applied in an initial dose of 4 mg/kg bodyweight of the animal, followed by weekly administration of doses of 2mg/kg bodyweight of the animal.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to apply the haloarylpyrazole compound including the elected species as taught by US patent 5,189,053 to any animals including dogs or cats with a reasonable expectation of success of getting the same effect since US patent 5,189,053 teaches the haloarylpyrazole compound is useful for controlling animal ecto- and endoparasites such as ticks.

With regard to the initial dose and weekly administration dose, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to optimize dosage of the compound for each animal and based on the severity of infestation. As anyone of ordinary skill in the art would appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infestation would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition and age of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover

because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 13-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US patent 5,189,053 as evidenced by US 2003/0199579.

As stated above in 102 rejection, US patent 5,189,053 teaches all the limitations of claims 1-5.

The reference differs from the instant claims 6-10 and 13-19 insofar as it does not specifically teaches that the animal is a dog or a cat and that the compound is applied in an initial

dose of 4 mg/kg bodyweight of the animal, followed by weekly administration of doses of 2mg/kg bodyweight of the animal.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to apply the haloarylpyrazole compound including the elected species as taught by US patent 5,189,053 to any animals including dogs or cats with a reasonable expectation of success of getting the same effect since US patent 5,189,053 teaches the haloarylpyrazole compound is useful for controlling animal ecto- and endoparasites such as ticks. Furthermore, US 2003/0199579, which teaches a compound effective for controlling fleas and ticks, which is used for domestic animals, pets such as dog and cat as well as for rodential animals such as mouse and rat (abstract and [0024]), is cited as only evidentiary reference to show that a compound effective for controlling tick is universally used for any animals including dog and cat as well as mice.

With regard to the initial dose and weekly administration dose, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to optimize dosage of the compound for each animal and based on the severity of infestation. As anyone of ordinary skill in the art would appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infestation would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition and age of the patient, the

duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)

Response to Applicant's arguments

In response to the argument regarding "deterring ticks from infesting an animal", the same response as stated above is applied.

With respect to claims 7, 8, 14 and 17, applicant argued that it would not have been obvious to optimize the dosage since Willis does not teach or suggest a "deterring effect". However, the "deterring effect" is within the teachings of the prior art as stated above.

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-18 of copending Application No. 11/698683. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '683 application are also drawn to a method for controlling a parasitic insect and/or acarid infestation comprising administering the same arylpyrazole compounds with the same core structure and substitution including the elected species, 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1H-pyrazole, wherein the term "parasitic insect and acarid" encompass ectoparasites, which include the egg, larval, pupal, nymphal, and adult stages of lice, fleas, mosquitoes, mites, ticks biting, or nuisance fly species in light of specification of '683 application (p10, [63]). Although the instant claims do not recite a nitroamine which is recited in the '683 claims, the instant claims recite the open language "comprising", which does not exclude additional unrecited elements (see MPEP 2111.03).

This is a provisional obviousness-type double patenting rejection.

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-11 and 19-20 of copending Application No. 10/577232. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '232 application are also drawn to a method for

controlling the infestation of an ectoparasite including ticks comprising administering the same arylpyrazole compounds with the same core structure and substitution including the elected species, 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1H-pyrazole. Although the instant claims do not recite one or more spinosyns which are recited in the '232 claims, the instant claims recite the open language "comprising", which does not exclude additional unrecited elements (see MPEP 2111.03).

This is a provisional obviousness-type double patenting rejection.

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-071818. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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